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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,972	08/29/2001	Yoshihide Murakami	213338	7743

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EXAMINER

REDDICK, MARIE L

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/941,972

Applicant(s)

MURAKAMI ET AL.

Examiner

Judy M. Reddick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Information Disclosure Statement**

1. The information disclosure statement filed 06/05/03 has been considered and scanned into the application file. The prior art to Otsuka et al (U.S. 4,608,249) cited by applicants and listed on a FORM PTO 1449 is noted with interest in teaching a drug-containing patching layer comprising a) an acrylic copolymer of 5 to 75 weight % of an (meth)acrylic ester having an ether group in the molecule, 85 to 15 weight % of an alkyl (meth)acrylate and 10 to 50 weight % of a polar monomer and 0.5 to 20 parts by weight per 100 parts by weight of acrylic copolymer of b) at least one adjuvant which includes carboxylic acid esters. A rejection, in the future, may be made based on Otsuka et al. However, since the outstanding rejection on the record still appears to be valid, a rejection at this time is not being made.

### **Claim Rejections - 35 USC § 102**

2. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-16 are rejected under 35 U.S.C. 102(b or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muraoka et al(U.S. 5,876,745) or Muraoka et al(U.S. 6,139,867).

As to claims 1-16, Muraoka et al'745 and Muraoka et al'867 teach(1 & 9) an adhesive composition for application to skin, which comprises an acrylic copolymer (100 parts by weight) obtained from a monomer mixture comprising a (meth)acrylic acid alkyl ester monomer (40-80 wt %), an alkoxy group-containing ethylenically unsaturated monomer (10-60 wt %) and a carboxy group-containing ethylenically unsaturated monomer (1-10 wt %), col. 2, lines 42-67, col. 3, lines 1-67 and col. 4, lines 1-6 of Muraoka'745 and col. 2, lines 37-67, col. 3, lines 1-67 and the claims of Muraoka et al'867 and a carboxylic acid ester (20-120 parts by weight), which is liquid or paste at room temperature(col. 4, lines 7-55 of Muraoka'745 and col. 4, lines 1-50 and the claims of Muraoka'867;(2 & 10) wherein the carboxylic acid ester is a glycerine ester of saturated fatty acid(col. 4, line 40 of Muraoka'745 and col. 4, line 36 and the claims of Muraoka'867);(3 and 11) wherein the saturated fatty acid has 8 to 10 carbon atoms(col. 4, lines 41-54 of Muraoka'745 and col. 4, lines 36-50 and the claims of Muraoka'867);(4 & 12) wherein, the saturated fatty acid having 8 to 10 carbon atoms is selected from the group consisting of a caprylic acid, a capric acid and a 2-ethylhexanoic acid(col. 4, lines 52-55 of Muraoka'745 and col. 4, lines 47-50 of Muraoka'867);(5 & 13) wherein, the glycerine ester is a triglycerine ester(col. 4, line 41 of Muraoka'745 and col. 4, line 36 of Muraoka'867);(6 & 14) wherein, the glycerine ester of saturated fatty acid is selected from the group consisting of triglyceryl caprylate, triglyceryl caprate and triglyceryl 2-ethylhexanoate(col. 4, lines 41 & 52-55 of Muraoka'745 and col. 4, lines 36 & 47-50 of Muraoka'867); (7 & 15) wherein, the adhesive composition is chemically crosslinked(col. 5, lines 1-29 of Muraoka'745 & the paragraph bridging cols. 4-5 of Muraoka'867); (8 & 16) wherein, the chemical crosslinking is performed using an organic compound selected from the group consisting of an organic peroxide, an isocyanate compound, an epoxy compound and a metal chelate compound(col. 5, lines 1-29 of Muraoka'745 & the paragraph bridging cols. 4-5 of Muraoka'867). Each of Muraoka'745 and

Muraoka'867 therefore anticipate the instantly claimed invention(see in particular Run 1). One having ordinary skill in the art would have readily envisaged the substitution of an acrylic copolymer, falling within the scope of the claims, for the acrylic polymer per Run 1 of each of patentees following the guidelines of Muraoka et al'745 at the paragraph bridging cols. 2-3 and col. 3, lines 53-58 and the guidelines of Muraoka et al'867 at the paragraph bridging cols. 2-3 and col. 3, lines 47-52. While patentees are silent relative to the gel fraction of the disclosed acrylic copolymers(see claims 1 & 9), it is tenable that this limitation may be met by the acrylic copolymers of each of Muraoka'745 and Muraoka'867 since the acrylic copolymer of each of patentees is essentially the same as and made in essentially the same manner as the claimed acrylic copolymer and in the absence of the USPTO to have at its disposal the tools nor facilities to make physical determinations of this sort. The onus to show that the acrylic copolymers of patentees do not possess the claimed gel fraction is shifted to applicants under the guise of *In re Fitzgerald*(619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980)) or *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34(CCPA 1977)).

Even if it turns out that the Examiner has somehow missed the boat and the claims are not anticipated by the disclosure of Muraoka et al'745 or Muraoka et al'867, it would have been obvious to the skilled artisan to extrapolate, from the disclosures of patentees, the precisely defined adhesive composition, as claimed, as per such having been within the purview of the general disclosures of patentees and with a reasonable expectation of success.

#### Response to Arguments

5. Applicants' arguments, see paper no. 15, filed 09/05/03, with respect to the rejection(s) of claim(s) 1-16 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Shirai et al(U.S. 5,543,151) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Further, Counsel is herein advised that a Terminal Disclaimer would preclude a future (provisional) obviousness-type double patenting rejection based on the claims of U.S. copending application 10/317,076.

6. Applicant's arguments filed 03/08/04 have been fully considered but they are not persuasive.

Relative to Muraoka et al('745 and '867)—Firstly, Counsel argues that none of the Runs disclosed by the Muraoka references provide an acrylic copolymer prepared from the particular three components, viz., (A) a (meth)acrylic acid alkyl ester monomer(40 to 80 wt.%), (B) an alkoxy group-containing ethylenically unsaturated monomer(10-60 wt.%) and (C) a carboxy group-containing ethylenically unsaturated monomer(1-10 wt.%). With all due respect to Counsel's opinion, following the guidelines of the Muraoka references, one having ordinary skill in the art would have readily envisaged the acrylic copolymer, as claimed. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

All disclosures in reference patent must be evaluated, including nonpreferred embodiments; A reference is not limited to disclosure of specific working examples. In re Mills and Palmer, 176 USPQ 196 (CCPA 1972).

Secondly, Counsel argues that one of ordinary skill in the art would not have been motivated to pick and choose the particular monomers among the numerous monomers listed and, to this end, the Muraoka references teach that, in addition to the alkyl(meth)acrylates, used as the main monomer component, the preferred polar monomers and vinyl monomers are *carboxyl-containing monomers*, hydroxyl-containing monomers, amido-containing monomers, *alkoxyalkyl (meth)acrylates*, *alkoxy-containing (meth)acrylic ester*, and (meth)acrylic esters containing an oxido bond in the side chain thereof which translates to not too much picking and choosing from a narrow selection of monomers would be involved. In any event, A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES"— when the species is clearly named, the species claim is anticipated no matter how

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many other species are additionally named.” Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) “The claims were directed to polycarbonate containing cadmium laurate as an additive. The court upheld the Board's finding that a reference specifically naming cadmium laurate as an additive amongst a list of many suitable salts in polycarbonate resin anticipated the claims. The applicant had argued that cadmium laurate was only disclosed as representative of the salts and was expected to have the same properties as the other salts listed while, as shown in the application, cadmium laurate had unexpected properties. The court held that it did not matter that the salt was not disclosed as being preferred, the reference still anticipated the claims and because the claim was anticipated, the unexpected properties were immaterial.” In re Sivaramakrishnan , 213 USPQ 441 (CCPA 1982) (emphasis added).

#### Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

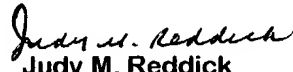
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571)272-1110. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571)272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Judy M. Reddick  
Primary Examiner  
Art Unit 1713

JMR   
05/24/04